DETAILED ACTION

1. Applicant's remarks, filed on 04/03/2008, are acknowledged.

Claims 1 – 32 are pending.

Claims 20 – 32 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

2. Applicant's election with traverse of Group III (claims 1 – 3 and 7 – 19, drawn to a method comprising administering an IgA receptor antagonist, wherein the inflammatory condition is asthma or other condition recited in claim 7) in the reply filed on 04/03/3008 is acknowledged.

Applicant further elected the Species of asthma as the specific condition and FcαR as the IgA receptor.

The traversal is on the grounds that the cited reference of Capra et al. does not show the lack of unity of invention, because the reference does not teach that the different inflammatory conditions which have been set forth as different inventions in the previous Office Action can be treated by IgA receptor antagonists.

This is not found persuasive because the reference anticipates the generic claim which encompasses the inflammatory diseases, and as such, Applicant's inventions do not contribute a special technical feature when viewed over the prior art of Capra et al.

However, in the interest of compact prosecution, examination has been extended to include the inventions of Groups I and II.

Claims 1 – 19 are presently under consideration.

3. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 – 14 and 16 – 19 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of the claimed method, because Applicant is not in possession of the generically recited "agent that can modulate an IgA receptor on a mesenchymal cell," or a generically recited "IgA receptor antagonist."

The instant specification discloses at page 19 that the recited "agents" or "antagonists" can be any type of substance, such as nucleic acids, proteins, carbohydrate, organic or inorganic compounds, small molecules, or drugs. The specification further provides description of some structural and functional features of antibodies, antisense oligonucleotides, and peptide mimetics within the scope of the invention (pages 19 – 24). A person of skill in the art cannot envision all the "agents" and "antagonists" encompassed by the scope of the claims as presently recited, other

than antibodies, antisense oligonucleotides, and peptide mimetics, because it was well known in the art at the time the invention was made that molecules having highly diverse structural and biochemical properties can affect cellular signaling. For example, Huang (Pharmacology and Therapeutics, 2000, 86: 201 – 215; see entire document) reviews e.g. on page 202 the daunting task faced by the skilled artisan in developing small molecule regulators of protein function, and notes that the process requires long periods of trial and error testing. Thus in the absence of a disclosure of sufficiently detailed, relevant identifying characteristics, such as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics, the skilled artisan cannot envision all the contemplated agents and antagonists encompassed by the instant claims.

Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993). The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001.

5. Claims 3 – 7 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

The specification does not provide a sufficient enabling description of a method "to treat an inflammatory condition," or asthma in particular.

The specification does not enable one of skill in the art to make and use the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification discloses that polymeric IgA increases cytosolic calcium in primary cultures of airway smooth muscle cells (pages 45 - 47), and that this effect is opposed by anti-J chain antibodies (page 47). The specification further discloses that

IgA enhances ICAM-1 expression in cultured synovial fibroblasts (pages 46 – 49), and increases tension ex vivo in dog tracheal smooth muscle strips (pages 49 – 50). The specification does not appear to have provided any data with regard to an effect an antagonist of pIgR or FcαR, such as an antibody, might have on mesenchymal cells, either in vitro or in vivo.

The instant claims are directed to a method of "treating" an inflammatory condition, such as asthma, which implies that the method is clinically effective. One of skill in the art is aware that the art of treating inflammatory diseases and asthma in particular, is highly unpredictable. For example, Heaney et al. (Lancet, 2005, 365: 974 – 976) review the difficulties in treating asthma, and conclude that "further studies are required," and treatment "might require alternative differing treatment strategies," such that "understanding the underlying mechanisms of refractory asthma is a future priority" (page 976 first column). Given the unpredictability of the art, the instant disclosure is not seen as sufficient to enable one of skill in the art to practice the claimed invention without undue experimentation.

6. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 – 2, 8 – 13, and 16 – 19 are rejected under **35 U.S.C. 102(b)** as being anticipated by Capra et al. (US Patent No. 6,063,905; of record; see entire document).

Capra et al. teach "mini IgA" polypeptides which include only antibody domains essential for dimerization and for binding of the dimers to the pIgA receptors (e.g. column 5, second paragraph). Capra et al. further teach methods comprising administering such mini IgA polypeptides to human subjects (e.g. columns 3 – 4, bridging paragraph).

One of skill in the art would readily understand that mini IgA polypeptides would compete with endogenous polymeric IgA antibodies (pIgA) for binding to their receptor (pIgR), and as such, constitute an IgA receptor antagonist.

Administering a polypeptide to a subject inherently results in contacting the cells in the subject with the polypeptide, including the types of cells recited in the instant claims. Further, since the methods taught by Capra et al. comprise the same method steps and utilize the same materials as the instantly claimed methods, the outcomes of performing the method steps of Hudson et al. are inherently the same as those of the instantly claimed methods. These include inhibiting of the inflammatory responses, modulating cytosolic calcium, inhibiting contraction, and inhibiting production of inflammatory mediators.

Therefore, the teachings of the reference anticipate the instant claimed invention.

8. Claims 1 – 12 and 14 – 19 are rejected under **35 U.S.C. 102(e)** as being anticipated by Hudson et al. (US Patent No. 7,192,582; see entire document).

Hudson et al. teach antibodies to FcαR (CD89), including scFv antibodies (e.g. columns 8 – 9, bridging paragraph), and wherein the antibodies block or inhibit IgA binding to CD89 (e.g. column 42, first paragraph). Hudson et al. further teach methods of treating diseases by administering said antibodies, wherein the diseases include rheumatoid arthritis, osteoarthritis, Crohn's disease, ulcerative colitis, Sjorgen's syndrome, and asthma (e.g. columns 28 – 29, bridging paragraph).

Administering an antibody to a subject inherently results in contacting the cells in the subject with the antibody, including the types of cells recited in the instant claims. Further, since the methods taught by Hudson et al. comprise the same method steps and utilize the same materials as the instantly claimed methods, the outcomes of performing the method steps of Hudson et al. are inherently the same as those of the instantly claimed methods. These include inhibiting of the inflammatory responses, modulating cytosolic calcium, inhibiting contraction, and inhibiting production of inflammatory mediators.

Therefore, the teachings of the reference anticipate the instant claimed invention.

9. Conclusion: no claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI, Ph.D./
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